

Institutional Review Board Expedited Review

Ouachita Baptist University

Expedited Review Categories

The IRB may use an expedited review procedure, in compliance with [45 CFR Part 46](#) for certain categories of research that involve no more than minimal risk to the subjects and in which the only involvement of human subjects will be in one or more of the following categories:

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
4. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
 - (a) hair and nail clippings in a nondisfiguring manner;
 - (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
 - (c) permanent teeth if routine patient care indicates a need for extraction;
 - (d) excreta and external secretions (including sweat);
 - (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
 - (f) placenta removed at delivery;
 - (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
 - (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
 - (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
 - (j) sputum collected after saline mist nebulization.
5. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

- (a) from healthy, nonpregnant adults who weigh at least 110 pounds; for these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
 - (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected; for these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
6. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
- (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
 - (b) weighing or testing sensory acuity;
 - (c) magnetic resonance imaging;
 - (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
7. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
- (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
8. Continuing review of research previously approved by the convened IRB as follows:
- (a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - (b) where no subjects have been enrolled and no additional risks have been identified; or
 - (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that

the research involves no greater than minimal risk and no additional risks have been identified.

Application Process

- Complete the IRB Human Subjects Review Application and other required documents.
- Ask your department chair or supervisor to review them.
- Email them to the IRB Chair.

Review Process

Expedited review shall be conducted by the IRB chairperson or by one or more of the experienced IRB members designated by the chairperson to conduct the review. The IRB member conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research. The reviewer shall refer any research protocol which the reviewer would have disapproved to the Full IRB for review. The reviewer may also refer other research protocols to the Full IRB whenever the reviewer believes that Full IRB review is warranted.

When the expedited review procedure is used, the IRB chairperson or member(s) conducting the review shall inform IRB members of research protocols which have been approved under the procedure.

At a convened IRB meeting, any member may request that an activity which has been approved under the expedited procedure be reviewed by the IRB in accordance with non-expedited procedures. A vote of the members shall be taken concerning the request and the majority shall decide the issue.